IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P., and SYNAPTECH, INC.,	)	
Plaintiffs,	)	Civil Action No. 05-451-KAJ
v.	)	
PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC.,	)	
Defendants.	)	

ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS OF DEFENDANTS PAR PHARMACEUTICAL INC. AND PAR PHARMACEUTICAL COMPANIES, INC.

Defendants Par Pharmaceutical Inc. and Par Pharmaceutical Companies, Inc. (collectively "Defendants"), through their undersigned attorneys, respond to the Complaint of Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc. (collectively "Plaintiffs") as follows:

1. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 1 and on that basis deny the allegations set forth therein.

2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 2 and on that basis deny the allegations set forth therein.

3. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 3 and on that basis deny the allegations set forth therein.

4. Defendants admit that Par Pharmaceutical, Inc. is a corporation incorporated and existing under the laws of the State of Delaware, and has its principal place of business at One Ram Ridge Road, Spring Valley, New York 10977. Defendants further admit that Par Pharmaceutical, Inc. is registered to do business and does business in the State of Delaware.

5. Defendants admit that Par Pharmaceutical Companies, Inc. is a corporation incorporated and existing under the laws of the State of Delaware. Defendants further admit that Par Pharmaceutical Companies, Inc. is registered to do business and does business in the State of Delaware. Defendants further admit that Par Pharmaceutical Companies, Inc. is the parent corporation of Par Pharmaceutical, Inc. and that Par Pharmaceutical, Inc. is a wholly owned subsidiary of Par Pharmaceutical Companies, Inc. Defendants deny the remaining allegations set forth in Paragraph 5 of the Complaint.

6. Defendants deny the allegations set forth in Paragraph 6 of the Complaint.

7. Paragraph 7 contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Plaintiffs filed a civil action asserting patent infringement arising under Title 35 of the United States Code, for alleged infringement of United States Patent No. 4,663,318 ("the '318 Patent"). Defendants further admit that, with respect to the claims against them, this Court has jurisdiction over the subject matter of Plaintiffs' claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. Paragraph 8 contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that this Court has personal jurisdiction over Par Pharmaceutical, Inc. for the purposes of this action. Defendants deny the remaining allegations set forth in Paragraph 8 of the Complaint.

9. Paragraph 9 contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that this Court has personal jurisdiction over Par Pharmaceutical Companies, Inc. for the purposes of this action. Defendants deny the remaining allegations set forth in Paragraph 9 of the Complaint.

10. Defendants admit that venue is proper in this district with respect to them pursuant to 28 U.S.C. §§ 1391(b) and 1400(b). Defendants deny the remaining allegations set forth in Paragraph 10 of the Complaint.

11. Paragraph 11 contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that to introduce a drug into interstate commerce that has not previously been approved by the Food and Drug Administration ("FDA"), a New Drug Application ("NDA") must be submitted to the FDA, including information required under 21 U.S.C. § 355(b). Defendants deny the remaining allegations set forth in Paragraph 11 of the Complaint.

12. Paragraph 12 contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that one may file an Abbreviated New Drug Application ("ANDA") for approval to market a generic version of a previously approved drug by the FDA, and that an ANDA must include information required under 21 U.S.C. § 355(j). Defendants further admit that whether the FDA will consider a drug to be bioequivalent to a listed drug is at least partially governed by 21

U.S.C. § 355(j). Defendants deny the remaining allegations set forth in Paragraph 12 of the Complaint.

13. Paragraph 13 contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that 21 U.S.C. § 355(j) does not require that an ANDA contain all of the same information required in an NDA. Defendants further admit that 21 U.S.C. § 355(j) at least partially governs what information must be included in an ANDA. Defendants deny the remaining allegations set forth in Paragraph 13 of the Complaint.

14. Paragraph 14 contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that according to 21 U.S.C. § 355(j), an ANDA must contain information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the generic version of the drug has been previously approved by the FDA. Defendants deny the remaining allegations set forth in Paragraph 14 of the Complaint.

15. Paragraph 15 contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that according to 21 U.S.C. § 355(a), no person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to 21 U.S.C. § 355(b) or (j) is effective with respect to such drug. Defendants deny the remaining allegations set forth in Paragraph 15 of the Complaint.

16. Defendants admit that Janssen Pharma is identified by the FDA as the holder of approved NDA No. 21-169 for galantamine hydrobromide tablets in dosages of Eq. 4 mg base, 8 mg base, and 12 mg base. Defendants further admit that February 28,

2001 is the date identified by the FDA as the date on which NDA No. 21-169 was approved. Defendants further admit that the sole indication of use for which galantamine hydrobromide tablets are approved by the FDA in NDA No. 21-169 is the treatment of mild to moderate dementia of the Alzheimer's type. Defendants deny the remaining allegations set forth in Paragraph 16 of the Complaint.

17. Defendants admit that a commercial formulation of galantamine hydrobromide approved by the FDA for the treatment of mild to moderate dementia of the Alzheimer's type is sold under the trademarks RAZADYNE® and/or REMINYL®. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 17 of the Complaint, and on that basis deny the allegations set forth therein.

18. Defendants admit that the '318 patent is listed in the FDA's Orange Book in connection with NDA No. 21-169.

19. Paragraph 19 contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that they have not previously challenged the listing of the '318 patent in the Orange Book. Defendants deny the remaining allegations set forth in Paragraph 19 of the Complaint.

20. Paragraph 20 contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that on or before May 17, 2005, Par Pharmaceutical, Inc. filed with the FDA an ANDA (No. 77-604) for galantamine hydrobromide tablets bioequivalent to the commercial formulation of galantamine hydrobromide marketed under the trademark REMINYL® and Paragraph IV certifications under 21 U.S.C. § 505(j)(2)(A)(vii)(IV). Defendants further admit that Par

Pharmaceutical, Inc. filed the ANDA and Paragraph IV certifications to obtain approval under 21 U.S.C. § 505(j) to engage in the commercial manufacture and sale of its proposed galantamine hydrobromide tablets before the expiration of the patents listed in the Orange Book for NDA No. 21-169. Defendants further admit that if Par Pharmaceutical, Inc. obtains such approval from the FDA for ANDA No. 77-604, Par Pharmaceutical, Inc. intends to market in the United States the galantamine hydrobromide products described in the ANDA, and that such marketing may occur before the expiration of the '318 patent. Defendants deny the remaining allegations set forth in Paragraph 20 of the Complaint.

21. Defendants admit that the condition of use for which Par Pharmaceutical, Inc. seeks approval in its ANDA No. 77-604 is the treatment of mild to moderate dementia of the Alzheimer's type, the same condition of use as that approved in NDA No. 21-169. Defendants deny the remaining allegations set forth in Paragraph 21 of the Complaint.

22. Defendants admit that the indication set forth in the proposed labeling submitted by Par Pharmaceutical, Inc. in its ANDA No. 77-604 is the treatment of mild to moderate dementia of the Alzheimer's type, the same indication as that set forth in the approved labeling for the commercial formulation of galantamine hydrobromide which is marketed under the trademarks RAZADYNE® and/or REMINYL®. Defendants deny the remaining allegations set forth in Paragraph 22 of the Complaint.

23. Defendants reincorporate herein by reference the answers contained in Paragraphs 1-22 above.

24. Paragraph 24 contains conclusions of law for which no response is

required. To the extent a response is required, Defendants admit that the '318 patent is entitled "Method of Treating Alzheimer's Disease" and states on its face that it was issued May 5, 1987. Defendants admit that a copy of the '318 patent was attached as Exhibit A to the Complaint. Defendants deny the remaining allegations set forth in Paragraph 24 of the Complaint.

25. Paragraph 25 contains conclusions of law for which no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegation set forth in Paragraph 25 of the Complaint, and on that basis deny the allegation set forth therein.

26. Paragraph 26 contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that a commercial formulation of galantamine hydrobromide is marketed under the trademarks RAZADYNE® and/or REMINYL®. Defendants deny that the conditions of use for which the commercial formulation of galantamine hydrobromide is approved fall within one or more valid claims of the '318 patent. Defendants state that they are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 26 of the Complaint, and on that basis deny the remaining allegations set forth therein.

27. Paragraph 27 contains conclusions of law for which no response is required. To the extent a response is required, Defendants state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 27 of the Complaint, and on that basis deny the allegations set forth therein.

28. Paragraph 28 contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations set forth in paragraph 28 of the Complaint.

29. Paragraph 29 contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations set forth in paragraph 29 of the Complaint.

30. Paragraph 30 contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations set forth in paragraph 30 of the Complaint.

31. Paragraph 31 contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations set forth in paragraph 31 of the Complaint.

32. Paragraph 32 contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that they had knowledge of the '318 patent prior to Par Pharmaceutical Inc.'s filing ANDA No. 77-604. Defendants deny that this knowledge can or does form the basis for a finding of willful infringement and as such deny the remaining allegations set forth in Paragraph 32 of the Complaint.

33. Paragraph 33 contains conclusions of law for which no response is required. To the extent a response is required, Defendants deny the allegations set forth in paragraph 33 of the Complaint.

First Affirmative Defense

34. The manufacture, use, offering for sale or importation of the galantamine hydrobromide tablets that are the subject of ANDA No. 77-604 will not infringe directly or indirectly any valid or enforceable claim of the '318 patent.

Second Affirmative Defense

35. Each claim of the '318 patent is invalid for failure to satisfy one or more sections of 35 U.S.C. §§ 101, 102, 103, 112, and 116.

Third Affirmative Defense

36. Par Pharmaceutical Companies, Inc. is not a proper party to this action.

WHEREFORE, Defendants Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. request that the Complaint be dismissed with prejudice and that Defendants be awarded the costs of this action, its attorneys' fees, and all other relief that this Court deems just and proper.

COUNTERCLAIMS

Defendant Par Pharmaceutical, Inc., for its counterclaims against Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc., alleges as follows:

The Parties

37. Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware with a principal place of business of One Ram Ridge Rd., Spring Valley, NY 10977.

38. On information and belief, Janssen Pharmaceutica N.V. is a wholly-owned subsidiary of Johnson & Johnson, and is a corporation organized and existing under the

laws of Belgium and has its principal place of business at Turnhoutseweg 30, B-2340 Beerse, Belgium.

39. On information and belief, Janssen, L.P. is a wholly owned subsidiary of Johnson & Johnson, and is a limited partnership organized and existing under the laws of the State of New Jersey and has its principal place of business at 1125 Trenton-Harbouton Road, Titusville, New Jersey, 08560.

40. On information and belief, Synaptech, Inc. is a company organized and existing under the laws of the State of New York and has its principal place of business care of Schwartz & Salomon, P.C., 225 Broadway, New York, New York 10007.

Jurisdiction and Venue

41. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

42. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

43. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and 1400(b).

44. There is an actual and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '318 patent.

Background

45. On information and belief, Janssen Pharma is the holder of the approved NDA No. 21-169 for galantamine hydrobromide tablets in dosages of 4 mg base, 8 mg base, and 12 mg base.

46. NDA holders are required to disclose to the FDA the patent numbers of patents claiming the drug for which the NDA is submitted or patents claiming the method

of using such drug. The FDA lists these patents in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"). On information and belief, Janssen Pharma caused the '318 patent to be listed in the Orange Book as a patent which claims the drug for which Janssen Pharma submitted NDA No. 21-169 or which claims a method of using such drug. On information and belief, Synaptech, Inc. is the record owner of the '318 patent and Janssen Pharma is the exclusive licensee.

47. Par Pharmaceutical, Inc. submitted its ANDA No. 77-604 to obtain FDA approval to engage in the commercial manufacture, use and sale of 4 mg base, 8 mg base, and 12 mg base galantamine hydrobromide tablets, prior to the expiration of the '318 patent. ANDA 77-604 contained a Paragraph IV certification under 21 U.S.C. §505(j)(2)(A)(vii)(IV) that the '318 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the product described in ANDA No. 77-604.

48. As Par Pharmaceutical, Inc. sought FDA approval to engage in the commercial manufacture of galantamine hydrobromide before the expiration of the '318 patent that is listed in the Orange Book, Par Pharmaceutical, Inc. sent letters dated May 17, 2005 to Janssen, L.P., Janssen Pharmaceutica N.V. and Synaptech, Inc., notifying each that Par Pharmaceutical, Inc.'s ANDA No. 77-604 was received by the FDA, and detailing the factual and legal bases to support Par Pharmaceutical, Inc.'s opinion that the '318 patent was invalid, unenforceable and/or not infringed by the manufacture, use or sale of the product described in Par Pharmaceutical, Inc.'s ANDA.

49. On June 29, 2005 Plaintiffs filed the instant suit asserting infringement of the '318 patent.

50. Plaintiffs' filing of the Complaint has created a reasonable apprehension on the part of Par Pharmaceutical, Inc. that Plaintiffs will assert that Par Pharmaceutical, Inc.'s making, using, selling, offering to sell, or importing of the product described in ANDA 77-604 infringes or will infringe the '318 patent.

COUNT I

51. Defendant repeats and realleges the allegations of paragraphs 38-50 of its counterclaims as if fully set forth herein.

52. All of the claims of the '318 patent are invalid for failure to satisfy one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or 116.

COUNT II

53. Defendant repeats and realleges the allegations of paragraphs 38-52 of its counterclaims as if fully set forth herein.

54. The manufacture, use, offering for sale or importation of the galantamine hydrobromide tablets that are the subject of ANDA No. 77-604 will not infringe directly or indirectly any valid or enforceable claim of the '318 patent.

RELIEF

WHEREFORE, Defendant Par Pharmaceutical Inc. respectfully requests that:

A. The complaint be dismissed with prejudice;

B. A declaratory judgment that the filing of Par Pharmaceutical Inc.'s ANDA No. 77-604 does not infringe any valid claims of the '318 patent;

C. A declaratory judgment that the manufacture, use, offer to sell, sale, and/or importation into the United States of America of Par

Pharmaceutical, Inc.'s products that are the subject of ANDA 77-604 do not and will not infringe any valid claims of the '318 patent;

D. A declaratory judgment that the '318 patent is invalid;

E. Defendant be awarded its costs in this action;

F. Defendant be awarded its attorneys' fees pursuant to 35 U.S.C. § 285; and

G. Such other and further relief as to the Court might seem just and proper.

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Dated: July 19, 2005
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Par Pharmaceutical Companies, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Philip A. Rovner, hereby certify that on July 19, 2005, the within document was filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following; that the document was served on the following counsel as indicated; and that the document is available for viewing and downloading from CM/ECF.

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I hereby certify that on July 19, 2005 I have sent by Federal Express the foregoing document to the following non-registered participant:

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